DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	2/3/2025-2/5/2025 FEI NUMBER 3003971400

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mary D. Hinckley, Medical Director

FIRM NAME	STREET ADDRESS
Reproductive Science Center of the San Francisco Bay Area, a Medical Corporation	100 Park Pl Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Ramon, CA 94583-4416	Reproductive Establishment

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

HCT/Ps from ineligible donors which were made available for limited use were not prominently labeled with the Biohazard legend and a statement warning of communicable disease risks.

Specifically,

The following ineligible donors, which were made available for limited use, were not prominently labeled with the biohazard legend and a statement warning of communicable disease risk. For example:

Donor	Donor Eligibility Determination	Communicable Disease Risk	Fertilized Oocytes Transferred	Tissues in Storage
Directed Ooycte [redacted]	Ineligible on	[redacted] based on screening.		fertilized ooctyes.
Directed Oocyte [redacted]	Ineligible on	[redacted] based on screening.		fertilized oocytes.
Directed	Ineligible on	[redacted] and	[redacted]	

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EMPLOYEE(S) SIGNATURE
Lesley Mae P Lutao, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao -S
Date Signed: 02-05-2025 15:01:27

DATE ISSUED
2/5/2025

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Semen (b)(6) (b)(7)(C)		risk based on screening		fertilized oocytes; [redacted] semen vials.
Directed Semen (b)(6) (b)(7)(C)	Ineligible on [redacted]	risk based on screening.	(b)(6) (b)(7)(C)	
Directed Semen (b)(6) (b)(7)(C)	Ineligible on	(b)(6) (b)(7)(C) core reactive		fertilized oocyte distributed to [redacted]

Since (b)(4), you have determined - directed semen donors ineligible, and - directed oocyte donors ineligible.

OBSERVATION 2

The summary of records for HCT/Ps from donors determined to be ineligible based on screening and released for limited use did not contain a statement noting the reasons(s) for the ineligibility.

Specifically,

Your summary of records fails to contain a statement noting the reason(s) for the ineligibility for directed semen and oocyte donors. For example:

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	Lesley Mae P Lutao, Investigator X Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 02-05-2025 15:01:27	2/5/2025

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Donor	Donor Eligibility Determination	Relevant Communicable Disease	Fertilized Oocytes Transferred	Tissues in Storage
Directed Oocyte	Ineligible on	based on screening		fertilized oocytes
Directed Oocyte	Ineligible on	risk based on screening		fertilized oocytes
Directed Semen	Ineligible on	risk based on screening		fertilized oocytes; semen vials.
Directed Semen	Ineligible on	risk based on screening		
Directed Semen	Ineligible on	core reactive based on testing		distributed to

SEE REVERSE OF THIS PAGE

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Lesley Mae P Lutao, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 02-05-2025 15:01:27

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Since [redacted], you have determined - directed semen donors ineligible, and - directed oocyte donors ineligible.

OBSERVATION 3

HCT/Ps for which the donor eligibility determination was not required were not prominently labeled with the appropriate warning statements.

Specifically,

You failed to prominently label the following cryopreserved fertilized oocytes that were subsequently intended for directed donation with the following: "[redacted]

(b)(4)

Cryopreserved Fertilized Oocytes Donors	Cryopreserved Fertilized Oocytes Donated	Cryopreserved Fertilized Oocytes Transferred & Stored
Oocyte [redacted] & Semen	(b)(6) (b)(7)(C)	transferred
Oocyte [redacted] & Semen		transferred; in storage.
Oocyte [redacted] & [redacted]		transferred; in storage.

Since [redacted] cryopreserved fertilized oocytes have been

(b)(4)

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subsequently intended for directed donation.

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	Lesley Mae P Lutao, Investigator	X Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 02-05-2025 15:51:27	2/5/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."